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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,446	10/24/2000	Suzana Petanceska	0630/IG184-US1	2608

7590
Darby & Darby P C
805 Third Avenue
New York, NY 10022

12/14/2001

EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/14/2001

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/695,446

Applicant(s)

PETANCESKA ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 7. 6) ☐ Other: _____

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DETAILED ACTION

Receipt of petition for extension of time and declaration both filed 4-5-01, IDS filed 4-6-01, and supplemental IDS filed 10-5-01 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is submitted that the specification is not enabled for prevention of a disease or disorder associated with Alzheimer's Disease (AD) as no evidence showing that complete avoidance of AD in all animals and cells. Indeed, it is submitted that complete avoidance of AD in all cells would not be possible to determine as AD appears to be a cumulative cognitive disorder resulting from cumulative neurodegradation. Accordingly, defining how much A β a cell might have before the cell degrades and the degree of the role of a particular cell in AD would not be possible. Amendment with "reducing the likelihood" or "reducing the probability" would overcome this rejection.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 8 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 16 require that the animal is ovariectomized (surgically removed ovaries) and orchidectomized (surgically removed testicles) (claim 7). Clarification regarding how an animal that could undergo surgery to have its testicles removed would also be able to undergo surgery to have its ovaries removed is requested as these are sex organs and a male animal would not have ovaries. It appears applicants intend "gonadectomy" and for purposes of examination, this claim is understood to require an animal only subjected to ovariectomy and not both orchidectomy and ovariectomy. Correction with gonadectomy would overcome this rejection.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 5-6, 20-21, and 23-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lee et al (WO 98/43647; hereafter '647).

'647 discloses administration of estrogenic compounds (17 β -estradiol) to reduce or maintain low levels of amyloid precursor protein (APP) for treatment of Alzheimer's

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Disease (AD) through reduction in amyloid peptides (abstract; page 7, lines 26-30; page 10, lines 10-14; page 21, line 5 - page 22, line 13). '647 also discloses a method for determining the capacity of a drug to inhibit the expression, production, or formation of APP in a cell comprising contacting an estrogenic drug with a cell culture that has the capacity to synthesize APP. The level of APP produced is then compared to a control (page 11, lines 20-29). Since the compositions of '647 and the instant claims appear to be the same and both are related to treatment of AD, it is submitted that the instant claims are directed to the mechanism of action of '647 and are thus inherent in '647 and the burden is shifted to the applicants to show a difference (MPEP 2112; *EMI Group North America Inc v. Cypress Semiconductor Corp* 60 USPQ2d 1423; *Ex parte Novitski* 26 USPQ2d 1389; *Atlas Powder Co. v. IRECO Inc* 51 USPQ2d 1943).

7. Claims 1-3, 5-6, 20-21, and 23-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lee et al (WO 98/43647; hereafter '647) in combination with Borchelt et al (1996) (see MPEP 2131.01 regarding multiple reference 35 U.S.C. 102 rejections).

'647 is relied upon for all that it teaches previously. Borchelt disclose a role for the ratio of A β 42 to A β 20 in the pathogenesis of AD. Accordingly, Borchelt is relied upon for disclosing a role for the ratio of A β 42 to A β 20 in the pathogenesis of AD. Therefore, since the compositions of '647 and the instant claims appear to be the same and both are related to treatment of AD, it is submitted that the instant claims are directed to the mechanism of action of '647 and are thus inherent in '647 and the

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burden is shifted to the applicants to show a difference (MPEP 2112; *EMI Group North America Inc v. Cypress Semiconductor Corp* 60 USPQ2d 1423; *Ex parte Novitski* 26 USPQ2d 1389; *Atlas Powder Co. v. IRECO Inc* 51 USPQ2d 1943).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-6, 15, 18-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Lee et al (WO 98/43647; hereafter '647).

'647 discloses administration of estrogenic compounds (17 β -estradiol) to reduce or maintain low levels of amyloid precursor protein (APP) for treatment of Alzheimer's Disease (AD) through reduction in amyloid peptides (abstract; page 7, lines 26-30; page

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10, lines 10-14; page 21, line 5 - page 22, line 13). '647 also discloses a method for determining the capacity of a drug to inhibit the expression, production, or formation of APP in a cell comprising contacting an estrogenic drug with a cell culture that has the capacity to synthesize APP. The level of APP produced is then compared to a control (page 11, lines 20-29). Since the compositions of '647 and the instant claims appear to be the same and both are related to treatment of AD, it is submitted that the instant claims are directed to the mechanism of action of '647 and are thus inherent in '647 and the burden is shifted to the applicants to show a difference (*MPEP* 2112; *EMI Group North America Inc v. Cypress Semiconductor Corp* 60 USPQ2d 1423; *Ex parte Novitski* 26 USPQ2d 1389; *Atlas Powder Co. v. IRECO Inc* 51 USPQ2d 1943). '647 does not teach use of equine estrogen as the estrogenic compound, however it would have been obvious to one skilled in the art at the time of the invention to use equine estrogen as it would have the same characteristics as non-equine estrogen since the structure is the same. Therefore the burden is shifted to the applicants to demonstrate the criticality of equine estrogen. '647 also does not specifically teach administering the estrogenic compound for at least ten days, however it would have been obvious to one skilled in the art at the time of the invention to administer the compound for at least ten days since '647 shows that administration reduces the probability of onset of AD and that this would be effective in estrogen deficient postmenopausal women. Thus, administration would occur indefinitely after menopause.

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11. Claims 1-6, 15, 18-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Lee et al (WO 98/43647; hereafter '647) in view of Borchelt et al (1996).

'647 is relied upon for all that it teaches as stated previously. '647 does not specifically teach a role for the ratio of A β 42 to A β 20 in the pathogenesis of AD.

Borchelt is relied upon for disclosing a role for the ratio of A β 42 to A β 20 in the pathogenesis of AD.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '647 and Borchelt to measure the amounts and/or ratio of A β 42 to A β 20 to determine whether a compound is effective at reducing these levels or ratio.

12. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Lee et al (WO 98/43647; hereafter '647) in combination with Borchelt et al (1996) and further in combination with Simpkins et al (1997). Claims directed to orchidectomy are further rejected in view of Williams and Stancel (Goodman and Gilman's, 1996).

'647 and Borchelt are relied upon for all that they teach as stated previously. Neither teaches orchidectomy or ovariectomy (OVX).

Simpkins is relied upon for teaching OVX as a model for postmenopausal changes.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '647, Borchelt and Simpkins to utilize OVX as a model for postmenopause and determination of the capacity of a drug to treat AD through measurement of amounts and/or ratio of A β 42 to A β 20.

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Williams and Stancel is relied upon for teaching synthesis of estradiol from testosterone.

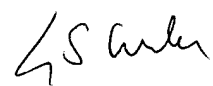
Accordingly, it would have been obvious to one skilled in the art at the time of the invention to utilize orchidectomized animals to study the capacity of a drug to treat AD in males.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

tw
December 11, 2001

